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November 22, 2002
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Achilefu et al.
Application No.: 09/757,333
Filed: January 9, 2001
Title: **VERSATILE HYDROPHILIC DYES**
Art Unit: 1619
Examiner: D. L. Jones
Atty. Docket No.: MRD-67

Cincinnati, OH 45202

November 22, 2002

Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Office Action mailed October 25, 2002 in the above-referenced application, applicants elect with traverse Group II (claims 1-20), drawn to compounds, compositions, and methods thereof. Additionally, in electing a particular

species, W5 and X5 are $C((CH_2)OH)_2$; Y5 is $-(CH_2)_2-CONH-Bm$; Z5 is $-(CH_2)_2-CONH-Dm$; A_3 is a single bond; A_3 , B_3 , C_3 and D_3 together form a 6-membered carbocyclic ring; a_5 is 1; R^{58} is galactose; each of R^{59} to R^{66} is hydrogen; Bm is Octreotate; and Dm is bombesin.

However, applicants respectfully assert that such a restriction is improper. At the outset, applicants note that all the claims are directed to the structure designated as formula 3. More specifically, claims 1-3 recite a compound, claims 4-17 recite a method of performing a procedure by administering the compound of formula 3, and claims 18-20 recite a composition including the compound of formula 3. Applicants now provide the following analysis in support of their assertion.

First, the Examiner's restriction forces applicants to fragment the invention they claimed within a single claim. Under *In re Weber, Soder, & Boksay*, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978) (copy attached) this is not permitted.

The invention in *Weber* related to cyclic diamine derivatives possessing a common psychotherapeutic property and was identified by a single generic formula expressed in Markush format. The instant invention relates to compositions possessing a common physiological property and the compositions are identified by a single generic formula (formula 3) expressed in Markush format.

In *Weber*, the court viewed the Examiner's restriction as tantamount to a refusal to examine. It held that the United States Patent and Trademark Office has the authority to restrict between claims of an application reciting one or more independent and distinct inventions, but does not have the authority to require an applicant to divide

up a single claim and present it in different applications; this would allow an Examiner, rather than an applicant, to define an invention in violation of 35 U.S.C. §121, ¶2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention", emphasis added). Weber at 332. While recognizing the need for efficiency in limiting each application to one invention, the court stated that

...in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights [of the applicant] are paramount.

Second, §803.02 of the MPEP states that if the claims have unity of invention, it is improper to refuse to examine "that which applicants regard as their invention". Unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature as being essential to that utility.

With regard to the instant application, all the claimed compounds share a structure as shown in formula 3, and have the same utility as diagnostic and therapeutic agents for visualization and detection of tumors, and also preserve the fluorescence efficiency of dye molecules, do not aggregate in solution, form starburst dendrimers, are capable of absorbing or emitting light in the near infrared regions of the electromagnetic spectrum, and can be rendered tissue-specific.

For the reasons discussed, applicants respectfully request that the Examiner reconsider the restriction requirement.

Applicants know of no fee due with this submission. However, if any fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account 23-3000.

Respectfully submitted,

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